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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|---|---------------------|---------------------|
| 09/668,555 | 09/22/2000 | Ypke Vincentius Johannes Maria van Oosterhout | 4541US | 2631 |
| 24247 | 7590 | 11/06/2006 | EXAMINER | |
| TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110 | | | | SCHWADRON, RONALD B |
| | | ART UNIT | | PAPER NUMBER |
| | | 1644 | | |

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/668,555 | VAN OOOSTERHOUT ET AL. | |

| | | |
|----------------------|-----------------|--|
| Examiner | Art Unit | |
| Ron Schwadron, Ph.D. | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 9/29/06 has been entered.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "disulfide bond containing chemical linker" in claim 1. Applicant has not indicated where said limitation finds support in the specification as originally filed. While the specification discloses the use of SMPT as a cross-linker, said compound has a unique chemical structure and properties not found in disulfide bond containing chemical linkers per se (it has a particular chemical structure, tertiary structure and has a hindered disulfide bond). There is no support in the specification as originally filed for the scope of the claimed invention (aka the claimed invention constitutes new matter).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Scannon (WO 89/06967).

Scannon teaches use of a pharmaceutical composition containing the immunotoxins antiCD3 antibody/ ricin A and antiCD7 antibody/ ricin A to treat GVHD (see page 4, first paragraph, page 6, first paragraph, page 12, page 13). Scannon teaches that the immunotoxin can be prepared by chemical linkage using the art known disulfide bond linker SPDP (see page 5, last paragraph and page 15, first incomplete paragraph). Scannon discloses that the antibody can be of the IgG isotype (see page 6, second paragraph) wherein IgG2B is one of the four art known types of IgG. Thus the routineer would at once envisaged IgG2B, because IgG2B is one of the four art known types of IgG. See *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978) and *In re Petering*, 301 F.2d 676, 681, 133 USPQ 275,280 (CCPA 1962). Furthermore, Scannon also discloses use of antibodies of the IgG2B isotype in Table 1 (such as OKT4, etc).

In the decision of the BPAI 4/28/06, the Board stated:

"Upon consideration of the reference, we find that while Scannon teach (e.g. page 9), alternative immunotoxin compositions, Scannon specifically teach "in one embodiment of the present invention, an immunosuppressive immunotoxin composition will comprise at least one pan T-cell immunoglobulin reactive agent, e.g., reactive with the CD3, CD5 or CD7 antigen clusters." In our opinion, one of skill in the art reading this teaching in Scannon would immediately envisage a small class of seven compositions with common properties. In re Petering, 301 F.2d 676, 681, 133 USPQ 275,280 (CCPA 1962). Specifically, compositions that will comprise a molecule reactive with: (1)CD3; (2) CD5; (3) CD7; (4) CD3 and CD5; (5) CD3 and CD7; (6) CD5 and CD7;or (7) CD3, CD5 and CD7. Stated differently, we understand Scannon's use of the phrase "at least one pan T-cell immunoglobulin reactive agent, e.g reactive with the CD3, CD5 or CD7 antigen clusters," to represent a short-hand way of expressing the seven compositions set forth above. In addition, we note that while the title of the Scannon reference is "immunosuppression with anti-pan T cell immunotoxin compositions," the only anti-pan T cell immunoglobulin

reactive agents taught by Scannon, are CD3, CD5 and CD7. See e.g., Scannon, page 9. Further, as set forth on page 4 of Scannon, "[t]he cytotoxic agent component of the immunotoxin is preferably a ribosomal inhibiting protein, such as ricin or ricin A-chain." Accordingly, we agree with the examiner's finding that Scannon teach a pharmaceutical composition containing the immunotoxins anti-CD3-ricin A and anti-CD7-ricin A."

Applicants comments regarding this analysis were further addressed in the BPAI decision of 7/31/06 denying a request for rehearing.

6. No claims are allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Serial No. 09/668555
Art Unit 1644

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